IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : **10/772,502**
Applicants : **David B. Rozema et al.**
Filed : **02/05/2004**
Art Unit : **1636**
Examiner : **Makar, Kimberly A.**
Docket No. : **Mirus.042.03**
For: **Polyvinylethers for Delivery of Polynucleotides to Mammalian Cells**

Commissioner of Patents
PO Box 1450
Alexandria, VA 22313-1450

Considered
KM 11/26/07

DECLARATION UNDER 37 C.F.R. §1.132

Dear Sir:

I, Dr. Sean Monahan, hereby declare as follows:

1. I have a Doctorate in Chemistry from the University of Wisconsin, Madison.
2. I am familiar with the above captioned application and with U.S. Patent 6,616,949.
3. I am familiar with the development of reagents for the delivery of compounds into mammalian cells.
4. I am the author of the attached statement regarding the nature of the polymers and particles described in U.S. Patent 6,616,949.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

9-19-07

Dr. Sean Monahan Date
Senior Scientist, Mirus Bio Corporation

As stated in their abstract, Meier et al. describe polymeric hollow particles, made from block copolymers, for delivery of agents to specific regions in a mammal. Under certain conditions, their particles possess increased permeability. This increased permeability allows molecules to enter or exit the hollow particle. Under separate conditions, their particle possess decreased permeability. This decreased permeability prohibits the entrance or exit of the molecule. Thus, their particles can be used to entrap a molecule and then release the molecule under the appropriate conditions, such as decreased pH. Delivery of the particle to a specific region in a mammal is accomplished by the attachment of a targeting group, such as an antibody, to the particle. While these hollow particles appear to be able to release their contents in response to a specific stimuli, such as pH, there is no indication they contemplate delivery to a target site inside the cell. The inventors of U.S. Patent 6,616,946 do not describe or suggest any property of the hollow spheres that would enable them to disrupt a cellular membrane.

Sean D Monahan 9-19-07

Dr. Sean Monahan date

(1) Claims directed to delivery of a polynucleotide to a cell, not inside a cell

(2) there is no demonstration that the polymers disrupt a cellular membrane.

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DECLARATION UNDER 37 C.F.R. §1.132

Dear Sir:

I, Dr. Zane Neal, hereby declare as follows:

1. I have a Doctorate in Cellular/Molecular Immunology from the University of Wisconsin, Madison.
2. I am familiar with the above captioned application and U.S. Patent 6,616,946.
3. I am familiar with antibody structure, function and uses.
4. Antibodies, as used in 6,616,946, would not be considered to possess membrane activity as defined the 11/06/2000.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Zane Neal 8/30/2007

Dr. Zane Neal, Date
Senior Scientist, Mirus Bio Corporation